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**UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration**

**Serenity Café
Decision And Order**

On December 2, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Serenity Café (Applicant), of Chicago, Illinois. The Show Cause Order proposed the denial of Serenity Café's application for a DEA Certificate of Registration as a Maintenance Narcotic Treatment Program, on the grounds that the Applicant does "not have authority to handle controlled substances in the state of Illinois," and because its registration would be inconsistent with the public interest. Show Cause Order, at 1 (citing 21 U.S.C. 824(a)(3) and 21 U.S.C. 823(f)).

Specifically, the Show Cause Order alleged that on January 26, 2011, Applicant, while doing business as Recovery Café, had voluntarily surrendered its DEA Certificate of Registration for cause. Id. at 1. The Order alleged that an investigation of Recovery Café found that it "failed to maintain the mandatory records required to be kept for controlled substances, had an unexplained shortage of approximately 199,476 mg of methadone, and left controlled substances in an open safe unattended." Id.

The Show Cause Order further alleged that Applicant had failed to disclose on its application that Recovery Café had voluntarily surrendered for cause its DEA registration. Id. at 2 (citing 21 U.S.C. 824(a)(1)). Next, the Order alleged that Applicant does not have a valid Illinois Department of Human Services Alcoholism and Substance Abuse Treatment and Intervention License as required by state law. Id. (citing 20 Ill. Comp. Stat. 301/15-5; Ill. Admin. Code tit. 77, 2060.201). Finally, the Order also notified Applicant of its right to request

a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for doing either, and the consequence for failing to do either. Id. (citing 21 CFR 1301.43).

On December 8, 2011, Diversion Investigators (DIs) personally served the Show Cause Order on Mr. Derrick Arna, who, according to the affidavit of a DI, is the Chief Executive Officer and owner of Serenity Café. GX 1, at 3; GX 6. Since the date of service of the Order, thirty days have now passed and neither Applicant, nor anyone purporting to represent it, has requested a hearing or submitted a written statement in lieu of a hearing. I therefore find that Applicant has waived its right to a hearing or to submit a written statement in lieu of a hearing, and issue this Decision and Final Order based on relevant evidence contained in the record submitted by the Government. 21 CFR 1301.43(d) & (e). I make the following findings of fact.

FINDINGS

Serenity Café is owned by Mr. Derrick Arna. GX 1, at 3. Mr. Arna is also the authorized agent of Recovery Café, a former Opioid Treatment Program in Chicago, Illinois, which, on January 26, 2011, voluntarily surrendered its DEA Registration for cause following a January 6, 2001 on-site inspection which found numerous violations. Id. at 1; GX 3. More specifically, during the on-site inspection, DEA DIs found that Recovery Café had multiple record-keeping violations. Id. at 2. These included, inter alia, that it: 1) failed to record on DEA Form 222s, the date of receipt and quantity of schedule II controlled substances it received; 2) failed to maintain accurate and complete controlled substance records; and 3) failed to maintain dispensing records for the methadone it dispensed, including the date of the dispensing and the name of the patient receiving the drug. Id.

In addition, the DIs performed an audit of its handling of methadone hcl (5mg & 40mg) for the period from October 19, 2009 to January 6, 2011. Id. The audit found that the clinic was

short approximately 199,476 mg of methadone. Id. Finally, on January 25, 2011, the DIs found that controlled substances were left unattended in an open safe. Id. The next day, Mr. Arna executed a voluntary surrender of Recovery Café's DEA registration.

On February 14, 2011, Mr. Arna filed an application under the name of Serenity Café for registration as a Narcotic Treatment Program – Maintenance, at the proposed address of 110 E. 78th Street, Chicago, Illinois. GX 2, at 1. Mr. Arna sought authorization to handle methadone, a schedule II narcotic controlled substance, and buprenorphine, a schedule III narcotic controlled substance. Id.

In Section 4 of the application, Mr. Arna was required to list Applicant's state of licensure, license number and its expiration date. GX 2, at 2. Mr. Arna completed only the state of licensure block, writing "Illinois" and the word "pending." Id. at 2.

In Section 5 of the application, Mr. Arna was required to answer four liability questions. Among them was question 2, which asked: "Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending?" Mr. Arna marked "NO," and in the area provided for explaining any "YES" answer, wrote "None." Id.

On February 17, 2012, following a hearing before a state Administrative Law Judge (ALJ), the Secretary of the Illinois Department of Human Services issued a Final Order on Applicant's application for state licensure. See In the Matter of Serenity Café at 1, 11 DASA 001 (Ill. Dep't Hum. Servs., Feb. 17, 2012). Adopting the ALJ's findings and report, the Final Order denied Applicant's application for a state license to provide both Level I Adult and Adolescent Outpatient Treatment and Level II Adult and Adolescent Intensive Outpatient Treatment, DUI Evaluation, DUI Risk Education, and Methadone as Adjunct Services. Id.

Accordingly, because Applicant does not possess a valid Illinois license to provide substance abuse treatment, I find that Applicant is not currently authorized to dispense controlled substances in the State of Illinois, the State in which it seeks registration. See 20 Ill. Comp. Stat. 301/15-5 (it is “unlawful for any person to provide treatment for alcoholism and other drug abuse or dependency ... unless the person is licensed to do so by the Department”); Ill. Admin. Code tit. 77, 2060.201 (“Substance abuse treatment and intervention services ... shall be licensed by the Department.”).

DISCUSSION

Under section 303(g) of the Controlled Substances Act (CSA), “practitioners who dispense narcotic drugs [in schedule II] to individuals for maintenance treatment . . . shall obtain annually a separate registration for that purpose.” 21 U.S.C. 823(g)(1) (emphasis added). Moreover, this provision imposes as a requirement of registration, that the applicant meet three conditions, including that “the applicant is a practitioner who is determined by the Secretary to be qualified . . . to engage in the treatment with respect to which registration is sought.” Id. 823(g)(1)(A) (emphasis added). Thus, it is clear that in order to obtain a registration authorizing the dispensing of schedule II narcotics such a methadone for maintenance treatment, the applicant must be (among other things), a practitioner within the meaning of the CSA.¹

¹ Likewise, the requirements of section 303(g)(1) “are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B). 21 U.S.C. 823(g)(2)(A) (emphasis added). This provision requires that the “the practitioner submit to the Secretary [of HHS] a notification of the intent of the practitioner to begin dispensing the drugs or combinations for” maintenance or detoxification treatment, “as well as to certify that “[t]he practitioner is a qualifying physician,” that “the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services,” and that “[t]he total number of such patients of the practitioner at any one time will not exceed the applicable number.” Id. 823(g)(2)(B) (emphasis added). Moreover, a practitioner’s notification to the Secretary must “identif[y] the registration issued for the practitioner pursuant to subsection (f) of this section.” Id. 823(g)(2)(D)(i)(II). See also 21 CFR 1301.28.

The CSA defines the term “practitioner” to mean “a physician ... pharmacy, hospital or other person licensed, registered, or otherwise permitted, by ... the jurisdiction in which he practices ... to distribute, dispense, [or] administer ... a controlled substance in the course of professional practice.” 21 U.S.C. 802(21). Likewise, in the case of practitioners, the CSA imposes, as a condition of registration, that it be currently authorized to dispense controlled substances under the laws of the State in which it engages in professional practice. See id. 823(f) (“The Attorney General shall register practitioners ... if the applicant is authorized to dispense ... controlled substances under the laws of the State in which he practices.”). Thus, DEA has long held that the possession of authority under state law to dispense controlled substances is an essential condition for obtaining and maintaining a DEA registration. See David W. Wang, 72 FR 54297, 54298 (2007); Sheran Arden Yeates, 71 FR 39130, 39131 (2006); Dominick A. Ricci, 58 FR 51104, 51105 (1993); Bobby Watts, 53 FR 11919, 11920 (1988).

As found above, the Illinois Department of Human Services has issued a final order denying Applicant’s application for the state licenses required to dispense controlled substances for the purpose of providing maintenance treatment. Therefore, Applicant is not a “practitioner” within the meaning of the CSA, and thus, it is not entitled to be registered. See 21 U.S.C. 802(21); 823(f); 823(g). Accordingly, its application will be denied.²

ORDER

² Because it is clear that Applicant is not entitled to be registered, it is not necessary to decide whether denial of its application is warranted under the public interest standard of 21 U.S.C. 823(f).

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 823(g)(1) & (2), as well as 28 CFR 0.100(b), I order that the application of Serenity Café for a DEA Certificate of Registration as a Narcotic Treatment Program, be, and it hereby is, denied. This Order is effective [INSERT DATE THIRTY DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Dated:
June 4, 2012

Michele M. Leonhart
Administrator

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